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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,918

09/05/2003

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EXAMINER

ROE, JESSEE RANDALL

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

08/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,918	Applicant(s) FORBES JONES ET AL.	
	Examiner Jessee Roe	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10,12-20,32-34,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10,12-20,32-34,53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-2, 4-8, 10, 12-20, 32-34 and 53-54 are pending wherein claims 3, 9, 11, 21-31, and 35-52 are canceled and claim 54 is new.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-8, 10, 12, 16-20, 32-34 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542).

In regards to claims 1-2, 4, 6, 8, 10 and 12, Smith ('542) discloses an alloy having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the table below.

Element	From Instant Claims (weight percent)	Smith ('542) (weight percent)	Overlap (weight percent)
Claim 1 (col. 4, line 23 – col. 5, line 11)			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05	0 – 2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Element	From Instant Claims (weight percent)	Smith ('542) (weight percent)	Overlap (weight percent)
Claim 2			
N	less than 20 ppm	0 – 0.05	less than 20 ppm
Claim 4			
Ti	less than 0.03	0 – 2.0	less than 0.03
Claim 6			
Ni	33 – 37	5 – 45	33 – 37
Cr	19 – 21	13 – 25	19 – 21
Mo	9 – 10.5	7 – 16	9 – 10.5
Claim 8			
N	less than 20 ppm	0 – 0.05	less than 20 ppm
Claim 10			
Ti	less than 0.03	0 – 2.0	less than 0.03
Claim 12			
Al	0.05 – 0.15	0 – 2.0	0.05 – 0.15

The ranges disclosed by Smith ('542) for cobalt, nickel, chromium, molybdenum, nitrogen, titanium, aluminum, and iron are within the ranges claimed of the instant invention. The Examiner notes that the disclosed composition of the alloy overlaps the the composition of the claimed invention. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the compositions disclosed by Smith ('542) because Smith ('542) discloses the same utility (alloy wire) throughout the disclosed ranges.

Still regarding claim 1, Smith ('542) does not specify wherein the alloy would include spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the composition of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 – col. 5, line 11). . Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the

same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, in absence of evidence to the contrary, it would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. See MPEP 2112.01 I.

With respect to the recitation "at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium;" and "no greater than 0.035 weight percent carbon", Smith ('542) discloses adding 0 to 2 weight percent aluminum in the (col. 5, lines 3-10) and no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11) that would form a wire or cable (col. 3, lines 64-75).

In regards to claim 5, the Examiner notes that neither the instant invention nor the alloy disclosed by Smith ('542) necessitate the presence of manganese, phosphorus, silicon or sulfur. Smith ('542) discloses that the carbon content and boron content would be maintained to less than 0.05 weight percent (col. 4, line 68 – col. 5, line 2).

In regards to claim 7, the Examiner notes that neither the instant invention nor the alloy disclosed by Smith ('542) necessitate the presence of manganese, phosphorus, silicon, or sulfur. Smith ('542) discloses that the carbon content and boron content would be maintained to less than 0.05 weight percent and the content of iron would be less than 6 weight percent (col. 4, line 23 – col. 5, line 2).

In regards to claim 16, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches adding no more of 2 weight percent each and no more than 4 weight percent total of aluminum, titanium, and zirconium to prevent embrittlement and grain boundary second phase formation and the oxygen content would be no more than 0.05 weight percent (which includes 0 weight percent) (col. 4, line 69 – col. 5, line 11). Smith ('542) further discloses the same alloy composition formed by a substantially similar process. Therefore, the material properties of the alloy would be expected to be similar. See MPEP 2112.01 I.

In regards to claim 17, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches adding no more than 2 weight percent each and no more than 4 weight percent total of aluminum, titanium, and zirconium (which includes 0 weight percent) (col. 4, line 69 – col. 5, line 11). Therefore, the alloy would not necessarily be comprised of titanium or the alloy may contain a very small content of titanium and hence be substantially free of titanium.

In regards to claim 18, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches adding no more than 0.05 weight percent each and no more than 0.10 weight percent (which includes 0 weight percent) of carbon, boron, oxygen, nitrogen or beryllium. Therefore, the alloy would not necessarily be comprised of nitrogen or the alloy may contain a very small content of nitrogen and hence be substantially free of nitrogen.

In regards to claim 19, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches yield strengths of at least 200,000 psi (200 ksi) (col. 5, lines 46-

63). Furthermore, Smith ('542) discloses the same composition made by a substantially similar process. Therefore, the properties of the product would inherently be similar.

See MPEP 2112.01 I.

In regards to claim 20, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches an alloy composition having the same composition as the instant invention and a process of making the alloy (vacuum induction melting and vacuum arc melting) that is substantially similar to that of the instant invention. Therefore, it would be expected that alloy would qualify for use in surgical implant applications under ASTM standard specification F 562.

In regards to claims 32-34, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches making the alloy into articles of manufacture including wire and cable (col. 3, lines 64-75). The wire would be made of the same composition as the instant invention and the process of making the alloy (vacuum induction melting and vacuum arc melting) is substantially similar to that of the instant invention. Therefore, it would be expected that the alloy would qualify for use in surgical implant applications under ASTM standard specification F 562.

In regards to claim 53-54, Smith ('542) discloses an alloy wire having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14 and col. 3, lines 64-75). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the table on the following page.

Element	From Instant Claims (weight percent)	Smith ('542) (weight percent)	Overlap (weight percent)
Claim 1 (col. 4, line 23 – col. 5, line 11)			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05 – 0.15	0 – 2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Still regarding claim 53, the Examiner notes that the instant invention would not necessitate the addition of manganese, phosphorus, or silicon because “no greater than” includes 0 weight percent. Smith ('542) discloses adding no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11).

The ranges disclosed by Smith ('542) for cobalt, nickel, chromium, molybdenum, nitrogen, titanium, aluminum, and iron are within the ranges claimed of the instant invention. The Examiner notes that the disclosed composition of the alloy overlaps with the composition of the claimed invention. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the compositions disclosed by Smith ('542) because Smith ('542) discloses the same utility (alloy wire) throughout the disclosed ranges (col. 3, lines 64-75).

Still regarding claim 53, Smith ('542) does not specify wherein the alloy would include spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the composition of titanium, nitrogen, and

carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 – col. 5, line 11). . Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, in absence of evidence to the contrary, it would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. See MPEP 2112.01 I.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as applied to claim 1, and further in view of Ototani et al. (US 4,820,485).

In regards to claims 13-15, Smith ('542) discloses a cobalt-based alloy, but Smith ('542) does not specify wherein the alloy would contain 5 to 20 ppm calcium (claim 13), 5 to 50 ppm calcium (claim 14), or 5 to 50 ppm cerium.

Ototani et al. ('485) disclose adding 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium) to a cobalt-, nickel-, or iron-based alloy in order to perform deoxidation, desulfurization, and denitrification of the alloy (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium), as disclosed by Ototani et al. ('485), to the cobalt-based alloy as disclosed by Smith ('542), in order to perform deoxidation, desulfurization, and

denitrification of the alloy, as disclosed by Ototani et al. ('485) (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Claims 20, 32-34 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as applied to claim 1, and further in view of Thompson (US 6,342,068).

In regards to claims 20, 32-34 and 54, Smith ('542) discloses a cobalt-based alloy that would be used as a wire or cable (col. 3, lines 64-75), but Smith ('542) does not specify that the cobalt-based alloy would be used as a stent (surgical implant device).

Thompson ('068) discloses that cobalt-based alloys would be used as stents because of their biocompatibility, fatigue resistance, and corrosion resistance (col. 6, lines 21-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the cobalt-based alloy, as disclosed by Smith ('542), as a stent, as disclosed by Thompson ('068), because cobalt-based alloys would have biocompatibility, fatigue resistance, and corrosion resistance, as disclosed by Thompson ('068) (col. 6, lines 21-34).

Still regarding claim 34, the Examiner asserts that the alloy disclosed by Smith ('542) would meet the ASTM standard specification F 562, because Smith ('542) discloses substantially the same alloy composition as that of the instant invention.

Response to Arguments

Applicant's arguments filed 28 May 2008 have been fully considered but they are not persuasive.

First, the Applicant primarily argues that the content of nitrogen disclosed by Smith ('542), which would be up to 0.05 weight percent (equivalent to 500 ppm), would exceed the less than 30 ppm nitrogen claim limitation by more than 16 times; the less than 30 ppm nitrogen would be critical to the performance of the claimed alloy; and cites 2131.03 ("If the claims are directed to a narrow range and the reference teaches a broad range...[i]t may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims." (citing *Atofina v. Great Lakes Chem. Corp.* 441 F.3d 991, 999 (Fed. Cir. 2006))).

In response, the Examiner notes that section 2131.03 of the MPEP deals with anticipation (i.e. U.S.C. 102), whereas the rejection is based on obviousness (i.e. U.S.C. 103). Although the range of up to 0.05 weight percent nitrogen (equivalent to 500 ppm nitrogen) would be broader than the instantly claimed range of 0 to 30 ppm nitrogen, the Applicant has failed to show that this range would provide unexpected results over the prior art range of 0 to 500 ppm. To establish unexpected results over a claimed range, the Applicant should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. MPEP 716.02(d)(II).

Second, the Applicant primarily argues, with respect to the Lippard Declaration of 24 August 2007, that one having ordinary skill would not have read Smith ('542) to teach or suggest limiting nitrogen in the Smith ('542) alloy to less than 30 ppm; Smith

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('542) does not state or suggest any reason why one would have undertaken the involved, time-consuming , and costly steps necessary to limit nitrogen in the alloy described by Smith ('542) to less than 30 ppm; and Smith ('542) does not teach or suggest a microstructure that is substantially free of titanium nitride and mixed carbonitride inclusions and instead include well-tolerated substantially spherical oxide inclusions..

With respect to the amount of nitrogen, the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. MPEP 2144.05 II. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. MPEP716.02(d)(II).

Furthermore, the Examiner notes that claim 1 recites "less than 0.7 weight percent titanium". Thus, claim 1 does not necessitate the presence of titanium. Smith ('542) discloses (col. 5, lines 3-11) that the presence of titanium would provide additional strengthening. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to omit titanium (and therefore titanium nitride) where additional strengthening would not be required or desired. MPEP 2144.04(II)(A).

Additionally, the Examiner notes that Smith ('542) applies vacuum arc melting and vacuum induction melting in addition to drawing, forging and rolling (col. 4, lines 23-42 and col. 5, lines 11-45), which would be the same or substantially similar to the processes of the instant invention (See Examples 1 and 2 of the instant invention).

Therefore, free of mixed carbonitrides and spherical oxide inclusions would be expected. MPEP 2112.01 I.

Third, the Applicant primarily argues that in the Response filed 24 August 2007 and in the Lippard Declaration, the alloy of claim 1 of Subject Application addresses a long-felt need and, until the claimed invention was made available, unmet need for an MP35N alloy having substantially improved fatigue resistance.

In response, the Examiner notes that with respect to the Lippard Declaration, Henry E. Lippard is named as an inventor in this Application and the "long-felt need" must be recognized, persistent, and not solved by others. Furthermore, the Applicant has not provided evidence that a lack of fatigue resistance was recognized by others (i.e. not the Applicant) for a long period of time without a solution nor has the Applicant provided evidence of any prior unsuccessful attempts. MPEP 716.04.

Fourth, the Applicant primarily argues that the alloy from which the wire discussed in the Myers Declaration was formed had a composition and microstructure satisfying each and every element and limitation in claim 1 of the Subject Application.

In response, the Myers Declaration is directed toward a wire whereas the independent claims are directed toward merely an alloy composition which is more broad than a wire and therefore would not be commensurate in scope with the evidence provided in the Myer Declaration. MPEP 716.03(a).

Fifth, the Applicant primarily argues that Mr. Myers directly interacted with FWM's customers for 35N LT wire and obtained their first hand comments regarding the product. Given Mr. Myer's direct and informed knowledge as to why FWM's customers

purchased 35N LT wire, his above quoted observation in declaration paragraph 7 is not merely an opinion but rather is direct evidence of FWM's customers preferences and that they increasingly prefer product over other available wire products suitable for their application and although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not the ultimate legal conclusion at issue.

In response, the Applicant's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention; the Applicant has not shown whether or not the sales of the 35N LT wire were based on heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the instant invention; and the commercial success of the 35N LT wire may have been attributable to extensive advertising and position as a market leader before the introduction of the patented product. MPEP 716.03(b)(I). Also, gross sales figures do not show commercial success absent evidence as to market share. MPEP 716.03(b)(IV).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Roy V. King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JR

/John P. Sheehan/
Primary Examiner, Art Unit 1793

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/656,918	FORBES JONES ET AL.	
	Examiner	Art Unit	
	Jessee Roe	1793	